REMARKS

Reconsideration and allowance of the pending claims is hereby respectfully requested in light of the Remarks presented herein.

Rejections under 35 U.S.C. §112, ¶ 2

Claim 11

Claim 11 stands rejected under 35 U.S.C. §112, ¶2 as allegedly being indefinite. Specifically, the Office Action states that the recitation in claim 11 of "heat-free" is indefinite since, "[i]t is not clear how the reaction to create the singlet oxygen could occur in a heat-free manner." *See* Office Action, pg. 2.

Applicant disagrees that the term, "heat-free" renders claim 11 indefinite. As noted in MPEP §2173.02, examination of a claim for compliance with the definiteness requirement under 35 U.S.C. §112, ¶2 should focus on whether that claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. That MPEP section further states that definiteness of claim language must be analyzed in light of certain criteria, one of which is the content of Applicant's disclosure. If a claim apprises a person of ordinary skill in the art as to its metes and bounds, it is not indefinite. In this way, the definiteness requirement serves a notice function by providing clear warning to others as to what constitutes infringement.

In view of the MPEP's elucidation regarding definiteness, it is evident that the term "heat-free" does not blur the metes and bounds of claim 11 in any way. One having ordinary skill in the art would be apprised of the metes and bounds of that claim, and would be able to determine what constitutes infringement. This is especially the case in view of Applicant's disclosure.

To be sure, Applicant's specification is replete with teachings of "heat-free" treatment. The specification states that the, "inventive methods are significantly less invasive; specifically,

the lesions may be created without surgery, without the use of any cardiac bypass procedures, and without the use of heat." *See* Applicant's Specification pg. 9, lines 19-21. Similarly, on page 15, line 11 the specification states that normally, "the step of forming the lesions is heat-free." Applicant teaches the application of light, together with a photodynamic drug, (*i.e.,* photodynamic therapy) to produce a lesion for treating cardiac tissue.

The application of light to an area to produce a lesion is not the same as the application of heat to produce a lesion. Having the potential for incidental heat to derive from a light source does not change this fact or make the term "heat-free" in claim 11 any less definite. It is clear from the specification what is meant by "heat-free." It is a comparative state that contrasts to the higher energy regions that produce higher temperatures. The claimed procedure does not follow that high temperature route.

Claim 11 clearly sets forth its metes and bounds. It recites that the method for treating cardiac tissue is "heat-free," and goes on to recite, as a positive method step, subjection of a cardiac tissue to a *light* source. The combination of a photodynamic drug with a light source produces a lesion. Heat does not. One having ordinary skill in the art would understand what would constitute infringement of claim 11.

In response to the Office Action assertion regarding the generation of the singlet oxygen, Applicant points to page 18 of the specification where it is stated that, "[w]hen the light is absorbed by a photosensitizer, it produces an unstable energy state that ultimately results in the generation of an excited singlet oxygen." To the extent that heat is released when light is absorbed during the generation of the excited singlet oxygen, the method does not become one of heat treatment. An ordinary artisan, in view of the dearth of disclosure relating to *light treatment* methods would understand what is meant by "heat-free." What words would you have us use that did not cover the possibility that potentially, a small amount of heat could be created during the generation of the singlet oxygen? Is it a certainty that such a reaction is exothermic?

Applicant notes that this is the first time a rejection of claim 11 under 35 U.S.C. §112, ¶2 has been levied, despite the recitation of the term, "heat-free" in originally filed claim 11.

The rejection of claim 11 under 35 U.S.C. §112, ¶2 is improper and should be withdrawn.

Rejections under 35 U.S.C. §102(e)

Claims 1, 11, and 16

Claims 1, 11, and 16 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,143,019 to Motamedi *et al.* ("Motamedi"). In support of this rejection, the Office Action states that, "Motamedi et al teaches a method for cardiac tissue ablation (lesion) using light activated substances with photodynamic therapy (Col. 6, lines 3-7) for modification of tissues responsible for cardiac arrhythmias (abstract). All light sources, including a single source, produce light in a predetermined pattern that will produce a predetermined result on sensitized tissue." *See* Office Action, pgs. 2-3.

Applicant points out that independent claims 1 and 11, recite a "light source arranged so as to produce a lesion in a pattern corresponding to the light source." The Office Action fails to address the claimed feature relating to "corresponding to the light source." Indeed, the Office Action assertion that "[a]ll light sources, including a single source, produce light in a predetermined pattern," overlooks this element and fails to address it in its entirety. It is not a predetermined pattern of light that Applicant claims. It is a light source arranged so as to produce a lesion in a pattern corresponding to that light source. Nowhere has the Office Action demonstrated a light source arrangement of this nature.

Motamedi does not teach or disclose a light source arranged so as to produce a lesion in a pattern corresponding to it. A device having lights arranged in a certain pattern or fashion, does not read upon a device that forms lesions in a pattern corresponding to that light pattern, unless those lesion patterns are explicitly set forth.

Accordingly, the rejection under 35 U.S.C. §102(e) is improper and should be withdrawn.

Claims 22 and 24

Claims 22 and 24 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,443,974 to Oron *et al.* ("Oron"). In support of this rejection, the Office Action states that, "Oron discloses a chatheter for biostimulation of cardiac tissue using electromagnetic radiation that may be visible light (abstract). The light emitting area is disclosed as being flexible with the radiating element in a cutaway section (window) and a lens for emitting the beam in an outward radial direction (Col. 22, lines 42-52). The radiating area is surrounded by the catheter body (opaque) and is linear for a length of 2-3 cm (Col. 22, line 56). The opaqueness of the catheter is implied by operation in contact with the tissue minimizes absorption by blood in the heart (Col. 23, lines 2-4)." *See* Office Action pg. 3.

Applicant disagrees with this rejection. Claim 22, from which claim 24 depends, recites that the light emitting region emits "substantially all light emanating from the device to produce a lesion in a pattern corresponding to the light emitting region." Again, the Office Action completely fails to address this element. Nowhere does Oron teach or disclose a light emitting region that emits substantially all the light emanating from it, to produce a lesion in a pattern corresponding to that region. Oron could not, for it is directed toward biostimulation, not photoablation, of cardiac tissue. Lesions are not disclosed, nor even suggested.

Accordingly, the rejection under 35 U.S.C. §102(e) over Oron is improper and should be withdrawn.

Rejections under 35 U.S.C. §103(a)

Claims 2-4 and 12-14

Claims 2-4 and 12-14 stand rejected under 35 U.S.C. §103(a) over Motamedi. In support of the rejection the Office Action states that, "[i]t is inherent that the light activated substances must be introduced into the tissue in some manner. Whether the photosensitizer is introduced locally or systemically would have been obvious to the skilled artisan."

Motamedi was discussed briefly above, and that discussion is relevant here for its support that Motamedi fails to teach or disclose each and every element of the currently rejected claims. Furthermore, Motamedi is not a useful reference for purposes of 35 U.S.C. §103 because it teaches away from the present invention. Specifically, Motamedi teaches induction of local hyperthermia in cardiac tissue in order to trigger the protective response of heat shock proteins. Heating of the heart tissue to obtain the cardioprotective effects of HSPs is described throughout the specification. *See, e.g.,* col 5, lines 12-18 and lines 34-38; *see also* col. 7, lines 22-30; col. 4, lines 21-26, etc.

Heating heart tissue is central to Motamedi's invention. This is evident from Motamedi's own assertion that his invention fills the need "for a method of directly heating the heart and inducing regional HSP expression, thus avoiding the limitations that may be induced during whole body hyperthermia." *See* col. 2, lines 32-36. Therefore, Motamedi does not, and could not, render any of the present claims obvious. A method of treating cardiac tissue by heating it teaches away from a method of treating cardiac tissue by a heat-free approach.

Accordingly, Applicant respectfully requests that the rejections under 35 U.S.C. §103(a) in view of Motamedi be withdrawn.

Claims 5-10 and 17-21

Claims 5-10 and 17-21 stand rejected under 35 U.S.C. §103(a) over Motamedi as applied to claims 1 and 11, and further in view of U.S. Patent No. 6,164,238 to Lesh ("Lesh"). In support of the rejection the Examiner states:

> "Motamedi is discussed above for treating cardiac arrhythmias, but fails to disclose specific treatment areas. Lesh teaches methods to electrically isolate specific areas of the hear using ablative means to treat arrhythmia. Both interrupt the cardiac electrical process by ablating (creating lesions). This establishes the PDT technique as an alternative equivalent to RF ablation for interrupting this activity. Lesh teaches that focal arrhythmia often originate from a tissue region along the pulmonary veins of the left atrium, and even more particularly in the superior pulmonary veins. The method of treating involves forming a circumferential conduction block, using an internal catheter with ablation means,

which is located either (a) along a circumferential path of tissue in a pulmonary vein wall which circumscribes the pulmonary vein lumen and transects the electrical conductivity of the pulmonary vein relative to its longitudinal axis, or (b) along a circumferential path of tissue in a left posterior atrial wall which surrounds a pulmonary vein ostium and electrically isolates the pulmonary vein and the ostium from a substantial portion of the left posterior atrial wall including the other of the vein ostia. Lesh further teaches an external procedure wherein a circumferential conduction block of one or more pulmonary veins may be performed in an epicardial ablation procedure, wherein an ablation element is either placed around the target pulmonary vein or is translated circumferentially around it while being energized to ablate the adjacent tissue in an "outside-in" approach. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the photodynamic techniques of Motamedi et al as an alternative equivalent to the RF ablative methods for treating cardiac arrhythmias in the patterns and areas as taught by Lesh."

Applicant strongly disagrees with this rejection. The references fail to teach or suggest all the claim limitations, there is no suggestion or motivation to modify the references or combine their teachings, and there would be no reasonable expectation of success upon doing so. Consequently, the Office Action fails to set forth even a *prima facie* case of obviousness, *see* MPEP §2143.

Claim 1, from which claims 5-10 depend, recites a method for producing patterned lesions by subjecting cardiac tissue containing a photodynamic drug to a "light source arranged so as to produce a lesion in a pattern corresponding to the light source." Similarly, claim 11, from which claims 17-21 depend, recites a "light source arranged so as to produce a lesion in a pattern corresponding to the light source." As described in detail above, Motamedi fails to teach or suggest this claimed light source arrangement, and Lesh fails to cure this deficiency.

Instead, Lesh describes methods of forming circumferential conduction blocks in the heart tissue of patients diagnosed with an atrial arrhythmia. The block isolates electrical conduction between opposite longitudinal portions of the pulmonary wall relative to the conduction block and along the longitudinal axis, preventing an atrial arrythmia. *See* col. 9, lines

64-67. Lesh teaches nothing of using light, or photodynamic therapy to treat a cardiac tissue, and similarly fails to suggest why using such techniques may be desirable.

One having ordinary skill in the art would not look to combine the conductive isolation methods of Lesh, with the HSP response methods of Motamedi. As noted above, the methods themselves, and the mechanisms by which they produce their effect, are very different. An attempt to combine these references would change the principle of operation each reference relies upon to produce its therapeutic effect. Thus, no reasonable expectation of success may be assumed upon combination of these references. The Office Action fails to provide any evidence to the contrary.

Therefore the rejections under 35 U.S.C. §103(a) are improper and should be withdrawn.

Claim 25

Claim 25 stands rejected under 35 U.S.C. §103(a) as unpatentable over Oron. In support of this rejection the Office Action states that, "Oron is discussed above but does not disclose LED's as a light source. The use of LED's is well known in the art and therefore it would have been obvious to use LED's in the device of Oron as a viable light source."

Oron was discussed above where it was noted that Oron fails to teach or describe each and every element of the claims, specifically, a light emitting region that emits "substantially all light emanating from the device to produce a lesion in a pattern corresponding to the light emitting region." Because Oron fails to disclose at least this element, a *prima facie* case of obviousness has not been established.

Accordingly, Applicant respectfully requests that the rejection of claim 25 under 35 U.S.C. §103(a) over Oron be withdrawn.

CONCLUSION

Applicant has responded to each matter of substance raised in the Office Action and submits that the case is in condition for allowance. If the Examiner believes that a telephonic discussion would expedite the prosecution of this case, he is urged to contact Applicant's attorney at the number listed below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **473912000100**.

Respectfully submitted,

Dated: July 28, 2003

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